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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,390	09/14/2005	Harold Neal Bramson	PU60144	6328

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EXAMINER	
GITOMER, RALPH J	

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
03/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/549,390	BRAMSON ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,12-14,19-24 and 28-42* is/are pending in the application.

4a) Of the above claim(s) *31-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,12-14,19-24 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment received 2/6/08 has been entered and claims 1, 3-7, 12-14, 19-24, 28-30 are considered here. Claims 31-42 are withdrawn from consideration.

Applicants have newly added the limitation to the claims that the detecting of binding is performed by Western blot or mass spec. In view of the amendments to the claims and arguments presented, the rejection of record under 35 USC 102(b) is hereby withdrawn. However a new rejection is made under 35 USC 103(a) in response to the newly added limitations to the claims including two references cited previously by applicants.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-7, 12-14, 19-24, 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Young in view of each of T'Jampens and Khandekar.

Young (J of Biological Chemistry) entitled "Pyridinyl Imidazole Inhibitors of p38 Mitogen Activated Protein Kinase Bind in the ATP Site" teaches on page 12118 column 1, a test inhibitor, SB203580, and p38 kinase were incubated with FSBA and ATP to determine the kinase inhibitory activity of SB203580. The FSBA is an ATP analogue that covalently modifies the kinase at lysine 72 and precludes ATP binding. On page 12119 Fig. 3 shows the effect of FSBA on the binding of SB203580 to p38 kinase.

The claims as amended differ from Young in that they include the limitation of using a method of Western blot or mass spec to determine binding of the kinase and analyte.

T'Jampens (FEBS Letters) entitled "Selected BTB/POZ Kelch Proteins Bind ATP" teaches on page 22 first column determining binding of FSBA and ATP by Western blot analysis.

Khandekar (J of Biomolecular Screening) entitled "A Liquid Chromatography/Mass Spec Based Method for the Selection of ATP Competitive Kinase Inhibitors" teaches in the abstract, a GC/MS method to monitor binding of ATP kinase inhibitors using FSBA.

It would have been obvious to one of ordinary skill in the art at the time of the invention to determine binding in the method of Young who teaches a radiolabeled kinase assay by either Western blot as taught by T'Jampens or by GC/MS as taught by Khandekar because all three are well known methods of determining binding and to employ the methods of T'Jampens or Khandekar for their art recognized function with the expected result would have a high expectation of success. To substitute one well known method of determining binding, such as radiolabeling, with other well known methods of determining binding such as Western blot or GC/MS, would have been obvious and is commonly performed in the enzyme assay art. No unexpected results are seen.

Claims 1, 3-4, 6-7, 12-14, 20, 22-24, 28-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for biotinylated FSBA, does not reasonably provide enablement for "an analyte". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim 1 and all occurrences the terms "an analyte" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such analyte would work in the instant invention.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.

2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.

3. Presence of working examples are only for biotinylated FSBA and extension to other compounds has not been specifically taught or suggested.

4. The nature of the invention is complex and unpredictable.

5. State of the prior art indicates that most related substances are not effective for the claimed functions.

6. Level of predictability of the art is very unpredictable.

7. Breadth of the claims encompasses an innumerable number of compounds.

8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Applicant's arguments filed 2/6/08 have been fully considered but they are not persuasive.

Applicants argue that undue experimentation would not be required to determine the analyte.

It is the examiners position that in the present instance, the claimed invention encompasses a veritable plethora of possible compounds of diverse structure and type and the use thereof as an analyte for binding to kinases. The inadequate disclosure coupled with a lack of representative examples and the art recognized unpredictability with respect to the effects of bioactivity of making even subtle changes to the chemical structure of the underlying compounds, thus preclude the making and use of compounds within the scope of the presently claimed invention by the skilled artisan without undue experimentation.

Claims 1, 3-7, 12-14, 19-24, 28-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1(a) “capable of binding” may be more positively stated as “which binds”. Method claim 1 is incomplete where there is no step to accomplish the preamble. Standard method steps may include determining and correlating where the independent claims do not specify what Western blot or mass spec are used for. Claim 22 may have a typo.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The Abstract of the Disclosure is objected to because it does not contain FSBA. Correction is required. See M.P.E.P. § 608.01(b).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

Ralph Gitomer
Primary Examiner
Art Unit 1657